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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,908	05/30/2006	Akio Imai	0152-0734PUS1	9354
2292 7590 11/05/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
11/05/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/580,908

**Applicant(s)**

IMAI ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 7-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated Jun. 24, 2009 have been entered and considered carefully.

Clams 2-6 have been canceled. Claims 1, 7-15 are pending.

2. Claims 1 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The amendment "in a reaction solvent of toluene in which appropriate quantities of soluble solvent is added" lacks antecedent basis in the specification and is new matter.

A survey of the specification indicated that it was described on pages 9-10:

*"2) The process according to 1), wherein a reaction solvent for the catalytic hydrogenation is water, an alcohol, acetic acid, an acetic acid ester, an ether, benzene, hexane, toluene, tetrahydrofuran, dioxane, or a mixed solvent thereof;*

*3) The process according to 1) or 2), wherein a reaction solvent for the catalytic hydrogenation is water, an alcohol, an acetic acid ester, toluene, tetrahydrofuran, or a mixed solvent thereof;*

*4) The process according to any of 1) to 3), wherein a reaction solvent for the catalytic hydrogenation is water, an alcohol, tetrahydrofuran, or a mixed solvent thereof;*

*5) The process according to any of 1) to 4), wherein a reaction solvent for the catalytic hydrogenation is tetrahydrofuran or hydrated tetrahydrofuran;*

*6) The process according to any of 1) to 3), wherein a reaction solvent for the catalytic hydrogenation is toluene, an alcohol, or a mixed solvent thereof;"*

On pages 13,

*"The amount of the solvent to be used is not particularly restricted, but is, for example, 7 to 30 times, and preferably 7 to 10 times of the volume of the compound of the structural formula (III)."*

Therefore, nowhere was how an "appropriate amount" was described. There are two examples using mixed solvent (examples 2 and 6) which are both 560 ml toluene and 140 ml of methanol. Therefore, the single mixture of toluene and methanol in 560/140 ml ratio does not offer any *description* of the claimed scope of "appropriate quantities" encompassing unlimited solvents in addition to toluene in un-defined ratio.

This is a *new matter* rejection. Removal of all new matter is required. In re Russmussen 210 USPQ 325.

3. The rejection of claims 1, 7-15 under 35 USC 103(a) over JP-A-179151 or JP-61-187674 in view of JP 64-79151 supplemented with US 4,898,841 and JP A-4-187674 with CA118 is maintained for reason of record.

The gist of applicants argument is that the comparative data of table 1 in the specification was significant.

Please note that nowhere in the specification any statistical analysis was made or any significant level was described. It was clearly delineated in the previous office action that purity of "final product" was not compared since the purity of the instant claims contain the additional step of purification by crystallization. Therefore, the vis-a-vis comparison on final product purity should be the instant process including crystallization with the product after silica gel chromatography.

In addition, any significance level must be supported by factual evidence not allegation which cannot offer any conclusion with respect to unexpectancy. For example, it is very confusing what is expected and what is unexpected and what is considered significant based on applicants' presentation on pages 12-13 of the Jun. 24, 2009 response. On pages 12-13 it was stated that the instant process produced product with significant high purity wherein on p. 13, the purity of example 2 of reference D3 is 98%. How is this 98% significantly different from the 98-99% of table 1 of page 12? Please note that variation of chemical process is "expected" even using the same procedure, repeated runs can differ in % purity. Without statistical analysis with side by side comparison, no conclusion can be drawn on such compilation of numbers.

It was further argued that the instant limitation of solvents (toluene or THF) are not expected to be operable with Raney nickel. As it was explained in the previous office action that

Raney nickel was disclosed by the prior art as an alternative catalyst of the exemplified palladium carbon. The solvent system has been also generically disclosed to include toluene and THF (see whole reference US 4,895,841 especially col. 16). In addition, toluene and THF are routinely used in chemical processes, thus one having ordinary skill in the art would be aware of the flammable nature with recognized precautions when such solvents are used. No factual evidence can be found that why the toluene or THF used with Raney nickel would be different from the enormous chemical reactions using toluene and THF as solvents. It is very confusing as to what is the nature of applicants argument: if it is unexpected result using Raney nickel and toluene or THF, then, no factual support was provided and the claims have not been limited to the specifics disclosed in the specification which is one solvent mixture of toluene/methanol 560/140 v/v; if the argument is the combination of using Raney nickel and flammable solvents, then no support for such combination can be found in the specification nor was any unexpected results commensurate with such scope were provided.

**4. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**5.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Oct. 28, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*